In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-0154V

Filed: July 28, 2023

Reissued for Public Availability: September 1, 2023

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ERIK LINDHOLM and LISA LINDHOLM, on behalf of K.E.L.,

Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

Erik Lindholm and Lisa Lindholm on behalf of K.E.L., Pro Se
Mark Kim Hellie, U.S. Department of Justice, Washington, DC, for Respondent

DECISION DENYING COMPENSATION[1]

Oler, Special Master:

On February 1, 2017, Erik Lindholm ("Mr. Lindholm") and Lisa Lindholm ("Ms. Lindholm") (collectively "Petitioners") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] (the "Vaccine Act" or "Program") on behalf of their minor son, K.E.L., alleging that K.E.L. suffered from injuries, including epileptic spasms, global developmental delay, acquired microcephaly, and encephalopathy as a result of a DTaP vaccination[3] he received on February 26, 2014. Petition

[1] Pursuant to Vaccine Rule 18(b), this decision was initially filed on July 28, 2023, and the parties were afforded 14 days to propose redactions. The parties did not propose any redactions. Accordingly, this decision is reissued in its original form for posting on the Court's website.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to subparagraph of 42 U.S.C. § 300aa (2012).

[3] K.E.L. received the Pediarix vaccine, a combined vaccine containing DTaP vaccine, hepatitis B vaccine, and inactivated polio vaccine. Ex. 3 at 31-32.

("Pet.") at 1. For the reasons discussed in this decision, I find that Petitioners have not demonstrated that the DTaP vaccine caused K.E.L.'s condition.

I. Procedural History

Petitioners filed a petition on February 1, 2017, alleging that their son, K.E.L., developed the Table injury of encephalopathy within 72 hours of vaccination with the diphtheria, tetanus, and pertussis vaccine ("DTaP" or "Pediarix"),[3] and alternatively that his epileptic spasms, global developmental delay, and acquired microcephaly were "caused-in-fact" by the DTaP vaccination K.E.L. received on February 26, 2014. Pet. at 1, 8, ECF No. 1. On February 6, 2017, Petitioners filed 23 medical record exhibits and Statement of Completion. Ex. 1-23, ECF No. 6-7.

On May 25, 2017, Respondent filed a Rule 4(c) report contesting entitlement in this case. Respondent argued that there is no evidence in the record to support a claim that K.E.L. suffered a Table encephalopathy following his receipt of the February 26, 2014 Pediarix vaccination. Respondent's Rep. at 7. Respondent noted that the affidavits submitted by Petitioners regarding onset "squarely contradict what petitioners told K.E.L.'s medical providers at the time they first sought medical treatment for his claimed injured and must be heavily scrutinized on that basis." *Id*. at 7-8. Thus, Respondent argued that Petitioners must pursue a causation-in-fact claim for which no expert report had been submitted. *Id*. at 8-9.

On February 19, 2018, Petitioners filed an expert report and curriculum vitae prepared by Dr. L. Douglas Wilkerson. ECF No. 32 ("First Wilkerson Rep."). On May 29, 2018, Respondent filed an expert report prepared by Dr. Michael H. Kohrman. Exs. A-B, ECF No. 34. Both Dr. Wilkerson and Dr. Kohrman filed supplemental expert reports on February 20, 2020, and June 22, 2020, respectively. ECF Nos. 49, 53. Thereafter, Petitioners filed a status report stating that they wanted their expert to respond to Dr. Kohrman's most recent expert report. ECF No. 54. However, over the next few months and after a number of motions for enlargement of time were granted, Petitioners' counsel filed a motion to withdraw from the case. ECF Nos. 59-60. I granted this motion on October 14, 2021, and Petitioners are currently acting *pro se*.

On December 15, 2021, I held a status conference with the parties to discuss the next steps in the case. Scheduling Order, ECF No. 73. Ms. Lindholm indicated that she was searching for a new attorney and requested 45 days to provide an update. *Id*. I granted that request. *Id*.

Over the next six to eight months, I ordered Petitioners to file numerous status reports to update me on their progress in securing new legal representation. ECF Nos. 73, 75, 77, 89. Petitioners corresponded with my law clerk on several occasions, but failed to contact my chambers or file a status report regarding their efforts after March 21, 2022. *See* Informal Communication Remark dated 4/20/2022. On April 20, 2022, I issued another order giving Petitioners 30 days to provide me with an update. *See* Scheduling Order dated 4/20/2022, ECF No. 77. Petitioners failed to contact my chambers or file a status report.

On May 26, 2022, after reviewing the records and expert reports filed in this case, I issued a scheduling order containing additional questions posed to Respondent's expert, Dr. Kohrman. ECF No. 81.

On August 8, 2022, I issued another order directing Petitioners to provide me with an update regarding their efforts to secure legal representation by September 7, 2022. ECF No. 89. I informed Petitioners that a failure to file a status report or contact my chambers would result in the issuance of an Order to Show Cause. *Id.* at 2. Petitioners did not contact my chambers or file a status report as directed. On September 9, 2022, I issued an Order to Show Cause for failure to prosecute and for failure to follow court orders, giving Petitioners until October 11, 2022, to file a response. ECF No. 90. In the Order to Show Cause, I notified Petitioners that their failure to provide a response "will be interpreted as a failure to prosecute this claim, and the petition shall be dismissed." *Id.* Petitioners have filed no response to date.

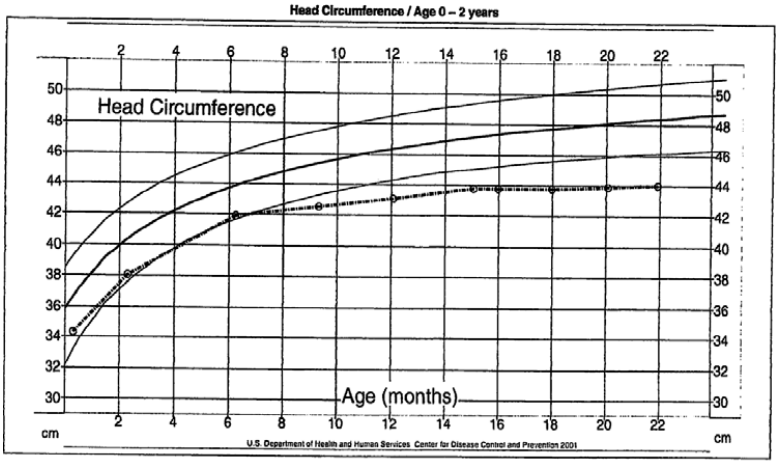
On September 30, 2022, Respondent filed another expert report prepared by Dr. Kohrman in response to the questions posed in my May 26, 2022 Order. With no further response from Petitioners, I find that this matter is now ripe for a decision.

II. Medical Records

A. Relevant Pre-Vaccination Medical History

K.E.L. was born on August 19, 2013 (Exhibit "Ex." 1), via cesarean section with no serious complications. *See generally* Ex. 2. For the first six months of life, K.E.L. received his routine childhood vaccines at the Avera McGreevy Clinic on schedule and without issue. Ex. 2 at 24-34, 92; Ex. at 3, 30-32.

K.E.L.'s head circumference measurement at birth on August 28, 2013, was 34.29 centimeters, over the 50th percentile. Ex. 2 at 14, 16. The head circumference measurements from birth to age 22 months are depicted in the following chart:



	Show	Date	Age		Head circumference		Bone age	
	check	mm/dd/yyyy	value	mm/yy	cm	%	years	Source
	☒	08/28/2013	0.29	months	34.30			M
	☒	10/28/2013	2.29	months	38.10	10%		M
	☒	02/26/2014	6.23	months	41.90	8%		M
	☒	05/29/2014	9.32	months	42.50	<3%		M
	☒	08/22/2014	12.10	months	43.10	<3%		M
	☒	11/20/2014	15.03	months	43.80	<3%		M
	☒	12/18/2014	15.97	months	43.80	<3%		M
	☒	02/18/2015	17.97	months	43.80	<3%		M
	☒	04/21/2015	20.06	months	43.90	<3%		M
	☒	04/21/2015	20.06	months	43.90	<3%		CN
	☒	06/16/2015	21.90	months	44.00	<3%		M

Ex. 16. No other pediatric records have been filed.

B. Post-Vaccination Medical History

On February 26, 2014, K.E.L. received the allegedly-causal Pediarix vaccine, his third dose of the three-dose series, during his six-month well-child visit. Ex. 2 at 190-91; Ex. 3 at 3, 31-32; Ex. 27 at 1. During this visit, the medical records note that K.E.L. had positive development for a six-month old; he babbled, reached for objects, rolled both ways, and was able to sit up unassisted for brief periods. Ex. 27 at 1. At this six-month well-child visit, it is noted that K.E.L.'s head circumference measurement had dropped to the 8th percentile. Ex. 16 at 1.

On April 2, 2014, 35 days later, K.E.L. was brought to his pediatrician, Dr. Shelby Eischens, for complaints of decreased appetite, cough, not acting himself which started four days prior. Ex. 27 at 5. K.E.L.'s mother also reported he had a low-grade fever the night prior, although she noted that he "seems happier this morning." *Id*. at 6. K.E.L. was noted to have swelling along his upper and lower gum lines and was assessed with nasal congestion. *Id*. at 7. Dr. Eischens felt that K.E.L.'s symptoms could be related to "teething vs mild viral URI." *Id*. She recommended topical VapoRub as needed with instructions to return if the child worsened or developed new symptoms. *Id.*

On May 29, 2014, K.E.L. returned to Dr. Eischens for his nine-month well child visit. Ex. 27 at 9. It was noted that K.E.L. had begun to crawl, that he looked for dropped toys, that he was able to say "mama" and "dada", he sat without support, and could transfer objects from hand to hand. *Id*. at 10. Dr. Eischens noted that K.E.L. appeared as a "healthy, happy baby" with "good bonding with mom." *Id*. His next well-child visit was noted to be at one year. *Id*. at 12. At this visit, the medical records document that K.E.L.'s head circumference had now fallen below the third percentile. Ex. 16 at 1.

On June 14, 2014, nearly 15 weeks after vaccination, K.E.L. (now 10 months old) was taken to the Emergency Department ("ED") at Brookings Health System for complaints of lethargy. Ex. 2 at 92-95. Ms. Lindholm reported to Dr. Andrew Ellsworth, the treating physician, that for the last month, K.E.L. had been "pretty lazy and laying around a lot." *Id*. at 92. She reported that the child's pediatrician, Dr.

Eischens, felt that K.E.L. may have been teething as he was experiencing low-grade fevers at the time. *Id.* Because K.E.L. could not see Dr. Eischens until June 26, 2014, Petitioners took him to the ED for evaluation. *Id*. Although K.E.L. was not experiencing any specific events at the time he was brought to the ED, Mrs. Lindholm wanted him evaluated because of an "episode of turning blue but woke up and then was fine" and that he did not "coo or talk anymore like he used to either." *Id*.

Treating physician, Dr. Jim F. Walery, noted that when he first walked in the room, K.E.L. was asleep and difficult to rouse. Ex. 2 at 93. Dr. Walery noted that K.E.L.'s ears were slightly red on the right, but his physical examination was otherwise normal. *Id*. Dr. Walery also noted that K.E.L. barely reacted to a blood draw, but 15 minutes later, he was awake, sitting in mom's lap, and "acting quite normal." *Id.* K.E.L. was able to roll over and sit up unassisted when laid on his stomach. *Id.* Dr. Walery noted "mild lethargy" in his assessment and instructed Petitioners to follow up with Dr. Eischens, K.E.L.'s pediatrician, for a review of all the lab work and further discussion regarding testing. *Id*. Dr. Walery also noted,

> [p]ossible other avenues to investigate would be blood exposure or perhaps even West Nile virus, a seizure disorder or some other complex genetic abnormality. Overall, this child just doesn't seem to appear normal at times. At other times he seems to be acting quite appropriately. I was impressed by his initial lethargy or disconnect from me during the initial exam but once I strongly stimulated him, he seemed to act more appropriate…

Id.

Another physician, Dr. Andrew Ellsworth, was consulted to perform a second opinion examination. Ex. 2 at 92-93. On examination, Dr. Ellsworth noted that K.E.L. was alert and "mildly fussy." *Id.* Ms. Lindholm reported that when K.E.L. was on his stomach, he did not move. *Id*. However, on examination, K.E.L. was able to sit up without assistance when laid on his stomach. *Id*. In the assessment, Dr. Ellsworth noted that K.E.L. appeared alert and had a "completely normal examination" at that time. *Id.* at 93. Dr. Ellsworth also documented that the results of a chest x-ray and basic metabolic panel were normal. *Id.*; Ex. 2 at 32. K.E.L. was discharged home with instructions to check his temperature twice daily and to administer Tylenol or Motrin if his temperature exceeded 100.5 degrees. *Id.* at 91. Petitioners were also instructed to follow up with K.E.L.'s primary care provider ("PCP"). *Id.*

Five days later, on June 19, 2014, K.E.L. presented to Dr. Germano Falcao at AMG Pediatric Specialists on follow up for complaints of seizures. Ex. 9 at 8; Ex. 10 at 12-13. Dr. Falcao noted on neurological exam that "Patient is noted to be sleepy (almost lethargic appearing). Reacts to light touch. Unable to assess further." *Id*. at 9. Concerns for infantile spasms were noted and an EEG study was ordered to assess for hypsarrhythmia.[4] *Id.*

[4] Hypsarrhythmia is defined as "an electroencephalographic abnormality sometimes observed in infants, with random, high-voltage slow waves and spikes that arise from multiple foci and spread to all cortical areas. It is seen most commonly in cases of jackknife seizures." Dorland. (2011). *Dorland's Illustrated Medical Dictionary E-Book*. London: Saunders.

Later that same day, June 19, 2014, K.E.L. underwent his first EEG study. Ex. 10 at 10-11. No EKG (cardiac) abnormalities were noted but his EEG[5] was abnormal with evidence of hypsarrhythmia patterns. *Id*. A pediatric hospitalist was notified with a plan to admit K.E.L. on an urgent basis for a workup of infantile spasms. *Id.* at 11. K.E.L. was also to start a six-week adrenocorticotropic[6] hormone therapy ("ACTH") medication course. *Id.*

K.E.L. was evaluated by Dr. Mina Hafalah after the EEG study was completed. Ex. 10 at 13. After reviewing his history and the results of the EEG study, Dr. Hafalah diagnosed K.E.L. with infantile spasms "by history and EEG recording (hypsarrhythmia)." *Id.* She requested that K.E.L. be urgently admitted in order to start a six-week course of ACTH therapy. *Id.*

From June 19, 2014, to June 25, 2014, K.E.L. was admitted to McKenna Hospital and University Health Center due to infantile spasms "and the need to initiate ACTH therapy." Ex. 25 at 40. In the history of present illness, it is noted that,

> [t]his is a previously healthy 10-month-old who had been well in his normal state of health up until a month back when the mother noticed that he was not acting himself anymore. He was becoming more lethargic, just wanted to be left alone, did not want to be held, and he then started having multiple episodes around 2 to 3 times a day of abnormal movements that initially they thought were scaring him, and that was brought to the attention of his pediatrician, but unfortunately at that point in time she was unable to look at any videos or witness the episodes herself, so she wanted the family to continue monitoring… he was then transferred to Dr. Germano Falcao for further management … Upon review of his developmental history, it is obvious that he is actually starting to lose developmental milestones unfortunately. Initially he was able to sit up at 6 months of age and he was able to roll over at 3 months of age, but since this happened, he is unable to sit up without support anymore, and he is not always maintaining eye contact…

Id. K.E.L. was admitted "with West syndrome" and ACTH therapy was initiated. *Id.* at 43.

A progress note dated June 20, 2014, stated "[t]his is a 10-month-old male who was in a normal state of health until a month prior when he began having increased lethargy, increased abnormal movement episodes which appear in clusters at times." Ex. 25 at 50. It was noted that K.E.L. had experienced two episodes since his admission, one episode lasting four minutes and another lasting three

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[5] An EEG or electroencephalogram is defined as "a recording of the potentials on the skull generated by currents emanating spontaneously from nerve cells in the brain. The normal dominant frequency of these potentials is about 8 to 10 cycles per second and the amplitude about 10 to 100 microvolts. Fluctuations in potential are seen in the form of waves, which correlate well with different neurologic conditions and so are used as diagnostic criteria." Dorland. (2011). *Dorland's Illustrated Medical Dictionary E-Book*. London: Saunders.

[6] "This medication is used to treat a certain type of seizure in children (infantile spasms). This medication is also used to treat conditions such as multiple sclerosis, arthritis, lupus, eye conditions, skin/kidney/lung diseases, and immune system disorders. It decreases your immune system's response to various diseases to reduce symptoms such as swelling, pain, and allergic-type reactions. Corticotropin is a hormone." https://www.webmd.com/drugs/2/drug-53492/acth-injection/details

minutes. *Id.* K.E.L. underwent a brain MRI on June 20, 2014, which was negative for any abnormalities. Ex. 25 at 123.

On June 24, 2014, while hospitalized, K.E.L. underwent another EEG exam to evaluate the etiology of the infantile spasms, for ACTH therapeutic drug monitoring, and for comparison with his prior EEG. Ex. 10 at 7. No EKG abnormalities were noted, but an abnormal EEG study documented a "moderately severe disorganized background more obvious during drowsiness" and "evidence of multifocal interictal epileptiform discharges." *Id.* at 8. The comments on the study stated that there was a remarkable improvement on the EEG background compared to patient's prior EEG recording dated June 19, 2014, that had a clearcut hypsarrhythmia pattern. This EEG is indicative of a positive response to ACTH treatment. In addition, since started ACTH, patient has been seizure free, (infantile spasms) for more than 48 hours…" *Id.*

On June 25, 2014, K.E.L. was discharged. Ex. 25 at 35. The medical records document that he remained afebrile during his admission. *Id*. at 36. K.E.L. experienced a total of three infantile spasms during his admission. *Id*. His weakness, alertness, and the number of spasms had all improved following ACTH therapy. *Id*.

The next month, on July 7, 2014, K.E.L. returned to Dr. Falcao for follow up. Ex. 9 at 4. The parents reported that K.E.L. was a "little irritable" but otherwise doing ok. *Id*. No seizure activity was reported. *Id*. On examination, Dr. Falcao noted that K.E.L. was awake, alert, active, and smiling during the visit. *Id*. Dr. Falcao also noted that "[t]his is a remarkable improvement from when I first met him, he appeared to be mostly lethargic and sleeping all the time." *Id.* at 6. The assessment described a "gladly remarkable improvement during the six-week course of ACTH" with "complete resolution of hypsarrhythmia pattern by repeat EEG" and normal brain MRI. *Id*. Dr. Falcao cautioned that K.E.L. was at increased risk of future seizures and developmental concerns and instructed Petitioners to return in four weeks for a repeat EEG. *Id*.

On the evening of August 3, 2014, and into the morning of August 4, 2014, K.E.L. was seen at the ED for complaints of nausea, vomiting and diarrhea. Ex. 2 at 111-115. The record from this visit noted that K.E.L. was seen earlier that day in the urgent care clinic for similar complaints. *Id*. His white blood count was elevated and there was a concern that he may have had a bacterial infection. *Id*. . The assessment was "[l]eukocytosis with associated nausea, vomiting and diarrhea." *Id*. at 112. K.E.L. received an antibiotic injection and was discharged with instructions that his parents keep him hydrated. *Id*.

On August 12, 2014, K.E.L. (11 months old) presented to Dr. Germano Falcao at AMG Pediatric Specialists for follow up on infantile spasms after the completion of ACTH injections. Ex. 9 at 1. Dr. Falcao noted that although K.E.L. was no longer receiving the injections, he was doing well with no seizure activity reported. *Id*. K.E.L.'s mother stated that he was recently ill with the flu, but he did not experience seizures during that visit. *Id*. K.E.L. was described to be sleeping better, although his appetite remained sporadic. *Id*. at 112-14.

K.E.L. underwent another EEG study immediately after this visit. Ex. 10 at 5. While no EKG heart abnormalities were noted, there were some EEG brain abnormalities observed during

the study. *Id*. The report noted that there was "a complete resolution of the prior documented hypsarrhythmia" pattern. *Id*.

On October 13, 2014, K.E.L. presented to Dr. Falcao for follow up regarding his infantile spasms. Ex. 9 at 1. After this visit, K.E.L. underwent another EEG evaluation for concerns of infantile spasms and breakthrough seizures. Ex. 10 at 1-2. The EEG results were abnormal and were indicative of "possible Lennox-Gastaut syndrome."[7] *Id*. at 2.

On November 6, 2014, K.E.L. was seen by Certified Nurse Practitioner, Kimberly Berg ("CNP Berg"), at the Minnesota Epilepsy Group, P.A., for a review of his EEG results obtained earlier that day and to discuss treatment options. Ex. 7 at 6. The medical record described that K.E.L. had a history significant for West Nile syndrome and infantile spasms status post ACTH therapy. *Id*. At the time, Petitioners reported that K.E.L. was averaging approximately two seizures per day, lasting one to two minutes and up to five minutes in clusters. *Id*. CNP Berg reviewed the results of K.E.L.'s current EEG, which was abnormal, and the results of previous EEGs and MRIs. *Id*. at 8. She recommended that K.E.L. begin Topamax, with increases in dosage over three to four weeks. *Id*. Clonazepam was also added in increasing dosages as tolerated. *Id*. She instructed Petitioners to call her in three weeks with an update on K.E.L.'s condition. *Id*.

On December 29, 2014, K.E.L. returned to CNP Berg in follow up. Ex. 7 at 1. K.E.L. had undergone an MRI of his head and brain earlier in the day which was normal. *Id*. at 12. CNP Berg noted that despite the new medications, K.E.L. continued to have seizures. *Id*. Petitioners reported that the seizures appeared to be less intense, although he was still experiencing one to four cluster seizures per day. *Id*. CNP Berg noted that K.E.L.'s head circumference had fallen below 5%. *Id*. CNP Berg instructed that the medications should be maximized and the dosing schedule completed. *Id*. She also encouraged Petitioners to obtain genetic testing in order to have an epilepsy panel completed. *Id*. Petitioners were instructed to follow up in three months. *Id*.

On January 13, 2015, Petitioners presented with K.E.L. to Dr. Laura Davis-Keppen at the Sanford Clinic in Sioux Falls, South Dakota, after being referred by Dr. Eischens for K.E.L. to undergo a genetic evaluation for his developmental delays and seizures. Ex. 11 at 1. Dr. Laura Davis-Keppen noted,

> The mother believes that his development was normal in early infancy. He was diagnosed with infantile spasms at 9 months of age, and then had a developmental regression… Parents were informed that his head circumference is relatively small but they believe this was not present at birth. There is a[] family history of smaller than average head circumference. *Id*. at 1-2. Dr. Davis-Keppen noted that she wanted to speak with K.E.L.'s pediatric neurologist to obtain records of all of his testing, including any genetic testing. *Id*. at 4. She noted that K.E.L.'s mother believed that the child's seizures were a result of an immunization, and she requested Dr. Davis-Keppen's opinion.

[7] Lennox Gastaut syndrome is defined as "an atypical form of absence epilepsy characterized by diffuse slow spike waves, often with atonic, tonic, or clonic seizures and intellectual disability; there may also be other neurologic abnormalities or multiple seizure types. Unlike typical absence epilepsy, it may persist into adulthood." Dorland. (2011). *Dorland's Illustrated Medical Dictionary E-Book*. London: Saunders.

Id. at 2.

On March 31, 2015, K.E.L. returned to Dr. Davis-Keppen for a follow up appointment. Ex. 11 at 20-25. After assessing K.E.L.'s current condition, Dr. Davis-Keppen recommended that a comprehensive epilepsy panel be ordered for further evaluation. *Id.* at 25. She stated that the "differential diagnosis for the cause of seizures is quite diverse and complex, and more than half of all epilepsies have been attributed to a genetic cause." *Id.* She noted that knowing the genetic basis of a patient's epilepsy is valuable for obtaining a definitive diagnosis, estimating prognosis, determining recurrence risk, and guiding treatment choices. *Id*.

K.E.L. underwent a comprehensive seven-day epilepsy evaluation at the Mayo Clinic by pediatric neurologist, Dr. Paul E. Youssef (supervised by Dr. Eric Payne and Dr. Katherine Nickels) from April 21-28, 2015. Ex. 8 at 74-76, 129-33. During intake, K.E.L.'s mother reported that K.E.L. started to have epileptic spasms in March 2014, when he was six to seven months of age.[8] Ex. 8 at 109. Following treatment with ACTH for six weeks in June 2014, K.E.L. was seizure free and experienced developmental improvement until September 2014. *Id.* Since then, he had continued to experience seizures. *Id.*

While at the Mayo Clinic, K.E.L. underwent a head MRI, which was normal with no structural abnormalities. Ex. 8 at 74. He also underwent a CSF (cerebral spinal fluid) examination which yielded normal results. *Id*. at 74-75. K.E.L. was also monitored in the Pediatric Epilepsy Monitoring unit from April 24, 2015, to April 27, 2015. *Id*. at 76. The results of the prolonged video-EEG were abnormal with one episode of whole-body spasm observed. *Id*. The report documented that these observations and results were consistent with an epileptic spasm. *Id*. At the conclusion of the seven-day evaluation, Petitioners were informed that the etiology of K.E.L.'s spasms, developmental delay, and acquired microcephaly remained undetermined. *Id*. at 76. Dr. Youssef noted in his report that he remained "highly suspicious that [K.E.L's] symptoms [were] of a genetic etiology" and arrangements had been made for more extensive metabolic testing. *Id.* Varied treatment options were discussed, and K.E.L.'s Clonazepam dose was increased. *Id*. at 75-76.

On May 7, 2015, Dr. Youssef noted that he had reviewed the most recent results of K.E.L.'s remaining biochemical and metabolic testing conducted during K.E.L.'s April evaluation. Ex. 8 at 74. Dr. Youssef noted "[i]n summary, our extensive biochemical and metabolic evaluation in the serum, urine, and cerebrospinal fluid has not found a biochemical, metabolic, or autoimmune etiology for [K.E.L.'s] seizures and developmental delay." *Id*.

On May 14, 2015, K.E.L.'s mother contacted Dr. Youssef with concerns that K.E.L. may have been having side effects related to the recent increase in his seizure medication, Clonazepam. Ex. 8 at 72. K.E.L.'s mother reported that over the prior two weeks, K.E.L. had a total of five epileptic spasms characterized by sudden head drop with flexion of the trunk and elevation of both upper limbs lasting several seconds. *Id*. She also reported that he went for a period of four days without any spasms. *Id*. She felt that the higher doses of Clonazepam had not been effective and caused K.E.L. to become fussier and his gait to become more unsteady. *Id*. Dr. Youssef counseled

[8] This is the first time Ms. Lindholm reported that K.E.L. began having seizures in March 2014.

K.E.L.'s mother on adjusting the medication dosages. *Id*. On June 2, 2015, K.E.L.'s mother called Dr. Youssef with similar complaints about an increase in the number of spasms. *Id*. at 71. Dr. Youssef again counseled on adjusting the medication dosages. *Id*.

On June 5, 2015, K.E.L. established care with Dr. Rick Kooima for his seizure disorder. Ex. 3 at 21. Dr. Kooima noted that K.E.L. had been followed by Dr. Falcao who treated him for infantile spasms. *Id*. It was noted that K.E.L.'s spasms had previously ceased for two months but then returned. *Id*. Currently, K.E.L. was documented as having 10 to 20 of these episodes in a row lasting up to 20 minutes. *Id*. The episodes were reported to happen four times per week. *Id*. The assessment was seizure disorder and developmental delay. *Id*. at 22. Petitioners were instructed to follow up with neurology at the Mayo Clinic and continue with the prescribed medications. *Id*.

On June 16, 2015, K.E.L. and his family returned to the Mayo Clinic for a follow-up visit. Ex. 8 at 66. At this time, the results of K.E.L.'s epiSEEK comprehensive epilepsy panel, which assessed 471 genes implicated in pediatric epilepsy, were available. *Id*. Dr. Youssef noted that there were multiple variants in three genes, but none of these specific genetic variants fit K.E.L.'s clinic phenotype. *Id*. Parental genetic testing was suggested. *Id*.

Dr. Youssef also discussed K.E.L.'s treatment since he was last seen in the clinic. Ex. 8 at 65. Unfortunately, despite the higher doses of medication, K.E.L. was continuing to experience epileptic spasms at a frequency of approximately three to five spasms per week. *Id*. at 65-66. The week prior, K.E.L. experienced a cluster of approximately 13 spasms within ten minutes while in the waiting room of a local ophthalmologist. *Id*. In terms of neurodevelopment, K.E.L. had not experienced any neurodevelopmental plateau or regression over the last two months. *Id*. It was noted that K.E.L.'s head circumference at this time had fallen to less than the third percentile by June 16, 2015. Ex. 6 at 1-2.

During an exam conducted by Certified Nurse Practitioner Laura Vanbeek on July 5, 2015, K.E.L. was noted to have trouble keeping his balance after starting a new seizure medication three weeks prior. Ex. 3 at 12. The medical records documented that he had a possible ear infection and instructed his parents to follow up with K.E.L.'s PCP if there was no improvement. *Id*. at 14.

On July 9, 2015, K.E.L.'s mother called Dr. Youssef at the Mayo Clinic to report that earlier that morning, K.E.L. had experienced a new type of seizure. Ex. 8 at 62. She reported that the seizure lasted three to four minutes with whole body stiffening, vocalizations, and that K.E.L. seemed to be trying to stand up. *Id*. K.E.L.'s mother reported that her son had an ear infection for which he was taking antibiotics. *Id*. After consultation, it was decided that there would be no medication changes. *Id*.

On July 18, 2015, K.E.L. was taken to the ED after a 12-minute seizure. Ex. 8 at 44. K.E.L. was with his family shopping when his mother reported that K.E.L. made a grunting noise and was subsequently unresponsive. *Id*. Intermittently, his tone would return to normal, and he tried to climb out of his stroller. *Id*. The family did not have any rescue medication with them at the time. *Id*. K.E.L. was admitted for monitoring. *Id*. at 46. No seizure activity occurred during this monitoring. *Id*. at 31. The EEG taken during this hospitalization did not show hypsarrhythmia. *Id*. at 32. Changes to medication dosages were planned and Petitioners were counseled on the use of

rescue medications. *Id*. at 33. K.E.L. remained hospitalized and was discharged on July 20, 2015. *Id*. at 29.

On July 21, 2015, K.E.L. presented to Dr. Payne at the Mayo Epilepsy Clinic.[9] Ex. 8 at 19. Dr. Payne noted that K.E.L. had recently begun experiencing clusters of tonic spasms that included guttural noises and lack of responsiveness during the episodes. *Id*. He noted that the spasms lasted up to 13 minutes in length and had been increasing in frequency over the prior two months. *Id*. K.E.L. had no clinical response to a new medication, Sabril, that had been administered to him at full dose two weeks prior. *Id*. Dr. Payne noted that K.E.L. may have been "evolving from a West syndrome phenotype towards a Lennox-Gastaut phenotype, although he has not met criteria for that yet." *Id*. at 19-20. Developmentally, it was noted that K.E.L. was making very slow gains. *Id*. at 20. Dr. Payne noted that the etiology of K.E.L.'s epileptic encephalopathy had yet to be determined. *Id*. No further genetic testing had been recommended at that time. *Id*. Dr. Payne adjusted K.E.L.'s medications based on the perceived efficacy of the dosages and types of medications in relation to K.E.L.'s seizure activity. *Id*. Petitioners were instructed to return with K.E.L. in three months. *Id*.

On July 27, 2015, K.E.L. was evaluated by Dr. Kooima at the Avery McGreevy Clinic after being hospitalized with croup the week prior. Ex. 3 at 6. K.E.L. was noted to have a "barky sounding cough at night" and was "more listless than normal" but was otherwise in no acute distress. *Id*. Petitioners were instructed to continue his medications as prescribed. *Id*.

On September 3, 2015, K.E.L., who was two years old at the time, presented to the ED with a three-day history of diarrhea, fever, dehydration, and acute gastroenteritis symptoms. Ex. 2 at 125. He was admitted for treatment. *Id*. The treating physician noted that K.E.L. had been seizure free for the past two weeks with additional Depakote therapy, but had a breakthrough seizure two days prior. *Id*. at 130. The review of systems section of the record noted that K.E.L. "has been walking and running up until this point in time. This is an improvement; his instability with gait is improving with the adjunct of therapy. His speech is still a little delayed with just one word." *Id*. at 131. K.E.L. was treated and discharged the next day. *Id*. at 124-25; 131-33.

On September 4, 2015, K.E.L. underwent a scan of his abdomen after experiencing diarrhea and fever. Ex. 2 at 31. The impression was "suspected colonic mural edema which could be seen in colitis." *Id*.

From September 2015 to August 2016, K.E.L. was seen in the ED several times for more routine illnesses such as fevers, rash, ear infections, bronchitis, and pharyngitis. Ex. 2 at 203-49. He continued to experience seizure activity during this time of varying severity and length. *Id*.

On November 7, 2016, K.E.L. presented for his three-year-old well child visit. Ex. 2 at 197. He was noted to be doing well with seizure control and had no seizures for the past three months. *Id*. The medical records documented that K.E.L. had some behavioral issues since staring preschool that week, as well as difficulty sleeping. *Id*. K.E.L. was noted to still have some instability with his gait, was not spoon feeding, had no specific words, but was working on potty training. *Id*. K.E.L. was described as a "very active child, biting new objects frequently." *Id*. at

[9] The record noted that Dr. Youssef had left the Mayo clinic. Ex. 8 at 19.

198. The assessment included abnormalities such as low ferritin, acquired microcephaly, developmental delay, seizure disorder, and insomnia due to medical condition. *Id*. at 200-01.

The most recently filed record is dated September 31, 2017, when K.E.L. was four years old. Ex. 28 at 1. K.E.L. was noted to have global developmental delay including absent expressive language and refractory epilepsy of unclear etiology. *Id*. The record states that his most recent EEG, conducted in November 2016, showed right posterior discharges representing an improvement. *Id*. At this appointment, the medical records describe that K.E.L. had no clear seizure activity with his last definitive seizure one- and one-half years prior. *Id*. K.E.L. continued to receive occupational therapy, physical therapy, and speech language therapy regularly. *Id*. He only had a few expressive words at this time and his mother was concerned about his language progress. *Id*. His health, otherwise, was noted to be good. *Id*.

III. Affidavits

A. Lisa Lindholm

Ms. Lindholm is K.E.L.'s mother. Ex. 4 at 1. Ms. Lindholm averred that her pregnancy with K.E.L. was uncomplicated. K.E.L. was born via cesarean section due to previous cesarean deliveries. Ms. Lindholm stated that K.E.L. was a "healthy little boy" from birth through February 26, 2014. She described that K.E.L. sat up, babbled, crawled and was a happy, playful child. *Id*.

Ms. Lindholm averred that K.E.L. received his routine vaccinations on October 28, 2013, and December 23, 2013, without incident. Ex. 4 at 2. On February 26, 2014, K.E.L. received his routine six-month vaccinations, including his third dose of the DTaP vaccine at the Brookings Clinic. *Id*. She stated that on the evening of February 26, 2014, K.E.L. cried "uncontrollably" as if any touch were painful to him. *Id*. Ms. Lindholm stated that toward the end of February 2014, she noticed that K.E.L. was experiencing jerking spells, as if he was startled by something. *Id*.

Sometime prior to March 4, 2014, Ms. Lindholm noticed that K.E.L. was "behaving lethargically and that he did not seem to even be present in his body." Ex. 4 at 2. She stated that K.E.L. appeared to not recognize his parents or other family members. *Id*. She stated that even when there was a lot of activity around him, K.E.L. would stare off into space as if he did not notice the activity around him. *Id*.

In her supplemental affidavit, Ms. Lindholm stated that she contacted K.E.L.'s pediatrician, Dr. Eischens, to inquire about K.E.L.'s "abnormal jerking spells," but was told that his symptoms were likely just a result of pain from teething. Ex. 28 at 1. Ms. Lindholm stated that she tried not to worry about K.E.L.'s jerking spells relying on this information. *Id*. Ms. Lindholm acknowledged that Dr. Eischens's records make no note of this telephone call and Ms. Lindholm has no telephone records to confirm this call. *Id*.

Ms. Lindholm stated that in the beginning of April 2014, she began to notice that K.E.L. was developmentally regressing in that he could no longer sit up on his own or attempt to crawl, both of which he was doing prior to February 26, 2014. Ex. 4 at 2. He was no longer lifting his head, or expressing any desire to eat, play or interact. *Id*. In her supplemental affidavit, Ms.

Lindholm stated that she contacted Dr. Eischens on April 1, 2014, to express her concern, but again, was told that it was likely just a response to teething. Ex. 27 at 1-2. When Ms. Lindholm brought K.E.L. in to see Dr. Eischens the next day for a cough, she stated that Dr. Eischens again failed to document the concerns about K.E.L.'s jerking spells. *Id*. at 2.

Ms. Lindholm described that K.E.L.'s issue with balance became apparent when he was nine months old in May 2014. She stated that they attempted to have his photos taken, but he would not sit up on his own, prompting the photographer to race over to prevent K.E.L. from falling over. Ex. 4 at 2. Ms. Lindholm also noticed that K.E.L.'s "spells" were occurring more often and involving more of his body. *Id*.

On June 14, 2014, Ms. Lindholm took K.E.L. to the ED when she noticed that he was hardly moving. Ex. 4 at 2. She noted that K.E.L. was experiencing unusual lethargy and behavior. Ms. Lindholm noted that even when K.E.L. was being examined and having blood drawn, he did not react at all. *Id*. However, no cause for his behavior was identified. *Id*.

Ms. Lindholm described that she took K.E.L. to AMG Pediatric Specialists for a thorough evaluation where he was diagnosed with infantile spasms. He was then admitted to the hospital to begin a six-week course of ACTH therapy. Ex. 4 at 3. For a few months after beginning ACTH therapy, K.E.L.'s spasms ceased. *Id*. While his EEG results continued to be abnormal, his seizure activity had improved. *Id*.

On October 13, 2014, K.E.L. experienced a seizure that was longer and more severe than prior seizures. Ex. 4 at 3. Ms. Lindholm reported that such seizures continued to happen approximately twice per day for the next several months. *Id*. She stated that since that time, K.E.L. has been examined by numerous doctors and specialists and has undergone a multitude of tests, including genetic testing. However, no test has identified the cause of K.E.L.'s condition. *Id*.

Ms. Lindholm stated that she was advised by various physicians, including the neurologists at the Minnesota Epilepsy Group, the doctors at the Mayo Clinic, and Dr. Falcao at AMG Pediatric Specialists to cease further vaccinations for K.E.L. until the cause of his condition had been identified. Ex. 4 at 3.

Ms. Lindholm stated that K.E.L. has been diagnosed with refractory epileptic spasms, global developmental delay, and acquired encephalopathy. Ex. 4 at 3. He receives speech, occupational, and physical therapy to address his developmental delays. *Id*. Ms. Lindholm stated that although K.E.L. is being treated, she has been advised that it is unlikely that K.E.L. will ever live independently. *Id*. at 4.

B. Erik Lindholm

Erik Lindholm is K.E.L.'s father. Ex. 5 at 1. He described K.E.L. as a "very happy, healthy little boy" who enjoyed playing with his parents, as well as his older brother and sister. *Id*. Like Ms. Lindholm, Mr. Lindholm described K.E.L. as inconsolable the evening of February 26, 2014, and into the morning of February 27, 2014. *Id*.

Mr. Lindholm stated that at the end of February 2014, he began to witness the "spells" that his wife described K.E.L. was experiencing. Ex. 5 at 2. He stated that K.E.L. would begin jerking or twitching as if something startled him. *Id*. Mr. Lindholm stated that he also began to notice that K.E.L.'s behavior had changed. He was no longer happy and interactive but rather lethargic and unreactive to the activity around him. *Id*.

Mr. Lindholm also discussed K.E.L.'s developmental regression. Ex. 5 at 2. Mr. Lindholm stated that K.E.L. could no longer sit up by himself, crawl, or babble. *Id*.

Mr. Lindholm averred that in May 2014, K.E.L.'s spells worsened. Instead of a slight jerking, K.E.L's whole body was involved in the spasms, and that the spasms occurred more frequently. Ex. 5 at 2. Mr. Lindholm acknowledged that the ACTH therapy seemed to work, but that by October 13, 2014, the seizures returned.

Mr. Lindholm stated that K.E.L. has been diagnosed with epileptic spasms, global developmental delay, and acquired microcephaly. Ex. 5 at 2. No cause has been identified for his symptoms. *Id*.

C. Bonnie Lindholm

Bonnie Lindholm ("Bonnie") is K.E.L.'s paternal grandmother. Ex. 19 at 1. Bonnie stated that she had been very involved in K.E.L.'s life since his birth, including his treatment and care following the February 26, 2014 DTaP vaccination. *Id*. Bonnie averred that from the time K.E.L. was born through February 2014, her grandson was "very heathy and happy." *Id*. She stated that he was babbling, sitting up, and attempting to crawl." *Id*. Bonnie stated that she noticed K.E.L. experiencing his first "spell" on approximately March 2, 2014. *Id*. at 1-2. Two days later, she noticed K.E.L. was lethargic and "no longer seemed to recognize me as he had previously…" *Id.* at 2. She stated that she tried playing with her grandson, but he would stare blankly. *Id*. Bonnie also stated that K.E.L. no longer attempted to crawl and had no interest in any of the activities he had previously enjoyed. She recalled that in May 2014, for K.E.L.'s nine-month pictures, she and Ms. Lindholm had to prop up K.E.L. for the photo because he could not support himself. *Id*. Bonnie stated that she was present for K.E.L.'s evaluation at the Mayo Clinic in April 2015. *Id*. She stated that when she asked about K.E.L.'s prognosis, she was told that K.E.L. would most likely never be able to live independently. *Id*.

D. Misty Alfson

Misty Alfson ("Ms. Alfson") is K.E.L.'s aunt. Ex. 20 at 1. Ms. Alfson stated that from birth through February 2014, K.E.L. was a "generally healthy little boy…. he was generally happy, playful, and interactive." *Id*. She recalled that in the weeks following the February 2014 vaccinations, she observed that K.E.L. was different; that he had regressed in his development and no longer seemed interested in playing or interacting. *Id*. She described several incidents where K.E.L. seemed uninterested and unresponsive to her and her family members. *Id*. at 1-2. Ms. Alfson stated that she drove Petitioners and K.E.L. to several appointments at the Minnesota Epilepsy Group and was present during the evaluations. *Id*. at 2. She stated that she asked many questions about the possible causes for K.E.L.'s seizure disorder and whether the vaccinations

were a possible cause. *Id*. While she stated that the physicians told her that the vaccinations were an unlikely cause, the doctors did instruct Petitioners to hold off on obtaining any further vaccinations for K.E.L. until the cause of his condition had been determined. *Id*.

E. Danielle Eppe

Danielle Eppe ("Ms. Eppe") is another of K.E.L.'s aunts. Ex. 21. In her affidavit, she stated that she and her family lived approximately one hour away from K.E.L. and Petitioners' home. *Id.* Ms. Eppe stated that around Christmas 2013, she recalled interacting with K.E.L. and having him make eye contact with her and smile. *Id*. On February 22, 2014, her father's birthday, she recalled seeing Petitioners and K.E.L. at a baseball game. *Id*. She stated that she fed K.E.L. with a bottle and again recalled making eye contact with him and observing him play with toys. *Id*. However in March or April 2014, she stated that she babysat for K.E.L. and noticed that his behavior was "very different." *Id*. at 2. Specifically, she stated that K.E.L. would not interact or respond to her, and he seemed very lethargic. *Id*. Again on April 20, 2014, when celebrating Easter, Ms. Eppe noticed that K.E.L. hardly seemed to notice her and would not interact or play. *Id*.

IV. Expert Opinions and Qualifications

A. Petitioners' Expert: Dr. L. Douglas Wilkerson, M.D.

1. Qualifications

Dr. Wilkerson received his medical degree from Emory University in Atlanta, Georgia, in 1969. ECF No. 32 (2) at 1 (hereinafter "Wilkerson CV"). Dr. Wilkerson completed his post-doctoral training in psychiatry and neurology (with a special competency in child neurology) and is board certified in pediatrics. Wilkerson CV at 1. Dr. Wilkerson has held a number of hospital and academic appointments. *Id.* at 1-2. He taught at the University of Pennsylvania School of Medicine in both the Department of Neurology and the Department of Pediatrics for 15 years. ECF No 36 (3); Fees App.; Ex. 2. Additionally, Dr. Wilkerson has been a pediatric neurologist at Bryn Mawr Hospital for nearly 40 years and has served as the Director of the Department of Pediatrics at the hospital from 1992-1998. *Id*. He is a member of numerous professional societies, including the American Academy of Neurology, the Child Neurology Society, the American Epilepsy Society, and the American Academy of Pediatrics as a fellow. *Id.* at 2-3. Dr. Wilkerson has published several original articles, reviews and chapters regarding pediatrics and neurology. *See id.* at 3.

2. Expert Reports

a. First Wilkerson Report

In Dr. Wilkerson's initial report, he opined that there are three "fundamental statements in this case which are straightforward and well supported by the evidence in this file." First Wilkerson Rep. at 1. First, he stated that K.E.L. was taken to a local neurologist because of jerking spells and was found to have infantile spasms "associated with the classic EEG abnormality of hypsarrhythmia." *Id*. Second, K.E.L. had a brief remission of his seizure disorder in response to

treatment, but which evolved to probable Lennox-Gastaut Syndrome. Dr. Wilkerson also noted that K.E.L.'s development slowed and his "previously normal head circumference trajectory has likewise slowed so that he now is microcephalic" *Id*. And third, K.E.L. received his routine immunizations on schedule "with a third administration of DTaP vaccine in late February, a bit less than four months before his initial presentation to the local neurologist because of jerking spells." *Id*. at 1-3. Dr. Wilkerson also observed that most known causes for K.E.L.'s seizures and microcephaly had been eliminated during the Mayo Clinic evaluation and subsequent testing. *Id*. at 3. Dr. Wilkerson opined:

> Since the findings of that evaluation eliminate all currently known alternative causes other than that of vaccine injury as the basis of the encephalopathy manifest in K.E.L., the results of that evaluation are consistent with the hypothesis of vaccine-related brain injury as its cause but, absent a consensus accepted biologic marker of vaccine-related brain injury, the hypothesis of vaccine-related brain injury was not scientifically proven. In other words, although it will never be scientifically proven that vaccine administration has caused brain injury in any individual until a biologic marker of that is eventually established, nevertheless, at this moment in time, the elimination of all other known causes of an encephalopathy than that of vaccine injury means that, more likely than not, vaccine-related brain injury is the cause of the encephalopathy manifest in K.E.L. Stated differently, from the medical standpoint of review of this file, it is apparent that, but for the administration of routine infantile vaccine in late February 2014, K.E.L. otherwise would not have developed infantile spasms and its associated encephalopathy.

Id.

Dr. Wilkerson went on to explain the difference between "typical" seizures and infantile spasms, noting that pinpointing the onset of the latter is exceedingly difficult due to the subtle and fleeting movements that are seizures, but not recognized as such. *Id*. at 4-5. Dr. Wilkerson described how with typical seizures, onset is easy to recognize as the first event is often a dramatic event comprised of a sudden loss of consciousness with body stiffening, convulsive jerking lasting for one to several minutes, and followed by a lengthy period of exhaustion and disorientation which is often referred to as the postictal state. *Id*. at 4. With infantile spasms, Dr. Wilkerson explained that "the individual seizures are fleeting in duration and, especially at the onset, often very subtle, at times producing only a nod of the head or barely perceptible jerk or movement of the shoulders, trunk or hips." *Id*. In addition, Dr. Wilkerson noted that seizure activity often occurs during sleep or during the time between sleep and waking when there is less observation of the child. Thus, the onset of seizures could be occurring, but unwitnessed. Dr. Wilkerson also noted that because infantile spasms are so rare, much more rare than "typical" seizures, "we virtually never hear the story of infantile spasms having a well delineated, clearly perceived onset that is comparable to the story told with 'typical' seizures…" *Id*. at 6. Thus, Dr. Wilkerson posited "an approximation of onset of K.E.L.'s spasms and behavioral changes within the week or so after the time of immunization … is a close fit with the NVICP criteria as can be expected." *Id*.

Dr. Wilkerson also explained that the recognition of an encephalopathy might not be evident until the child progressed far enough in development to recognize delays in reaching milestones. First Wilkerson Rep. at 7. For example, if an infant were unable to stand or walk at 10 to 14 months, recognition of a problem may occur, but the encephalopathy "would have been silently present long before." *Id*. Dr. Wilkerson noted that the same concept also applies to microcephaly, when by the time of the microcephaly is observed, the progression has occurred long before. *Id*.

Dr. Wilkerson next discussed "primitive responses" noting that normal primitive responses typically extinguish in infants at a point prior to those in K.E.L. *Id*. at 7. Given this clinical picture, Dr. Wilkerson posited that K.E.L.'s encephalopathy occurred at approximately six months of age. *Id*.

Dr. Wilkerson's conclusions at the end of report are that: (1) K.E.L. was normal at birth and for the first six months of his life; (2) at 10 months of age, K.E.L. was diagnosed with infantile spasms and that these spasms began, more likely than not, at about six months of age; (3) the diagnosis of infantile spasms occurred much later than the noted onset of symptoms described in the medical records; (4) the outcome of K.E.L.'s disorder has been poor; (5) there is a lack of information in the medical records that can pinpoint the onset of K.E.L.'s disorder; (6) no cause was identified for K.E.L.'s infantile spasms despite the thoroughness of testing; (7) there is a timely and causal link between the onset of K.E.L.'s spasms and the DTaP vaccine, particularly the pertussis component; (8) "there was a timely and causal linkage between the onset of the encephalopathy at approximately six months of age and vaccination; and (9) the preponderance of evidence at the level of current scientific understanding, as Dr. Wilkerson understands it, supports the medical conclusion that

> more likely than not, there is a significant causal contribution to the encephalopathy present in K.E.L. which is attributable to the immediate proximate vaccine administered to him in late February 2014. Stated differently, more likely than not, but for the vaccine administration of February 2014, K.E.L. otherwise would not have developed infantile spasms or the related encephalopathy.

Id. at 9.

b. Second Wilkerson Report

In Dr. Wilkerson's second report ("Second Wilkerson Rep."), prepared after Respondent's expert's report was filed (prepared by Dr. Kohrman), Dr. Wilkerson disagreed with Dr. Kohrman's conclusion that K.E.L. had progressive microcephaly with the onset occurring at two months of age, and therefore concluding that the DTaP vaccination could not have caused his microcephaly or infantile spasms. Second Wilkerson Rep. at 1. Dr. Wilkerson explained that "measurement of head circumference is difficult and subject to both interobserver variance and single observe inconsistency, owing to the inherent difficulty of measuring the longest circumference of an egg-shaped object and particularly so under the circumstances…" *Id*. He stated that because head circumference is typically measured by different staff members at different visits, that the likelihood of interobserver variance is great. *Id*. at 1-2. As a result, he opined that there is

"legitimate uncertainty about the start of the abnormal trajectory leading eventually to the microcephalic range." *Id*. at 2.

Dr. Wilkerson explained that abnormally small head circumference is generally a result of abnormal brain development. However, with K.E.L., Dr. Wilkerson noted that there were no developmental abnormalities until approximately eight or nine months of age ("[t]he first medically recorded note of neurodevelopmental abnormality was the report of persisting neonatal responses described when K.E.L. was around eight- or nine-months age"). *Id*. at 2. At this time, there was a description of persisting neonatal primitive responses, which Dr. Wilkerson stated should have diminished around age two or three months. *Id*.

Next, Dr. Wilkerson observed that no specific cause was identified for K.E.L.'s condition, allowing a vaccine-induced encephalopathy to remain as a possible cause. *Id*. Dr. Wilkerson reiterated his conclusions that "K.E.L. has a severe encephalopathic process with onset at point proximate to his age of 6 months and that the administration of his third vaccine dose of the DTaP" and thus, he fulfills the requirements for compensation under the Vaccine Act. *Id*. at 4.

B. Respondent's Expert – Dr. Michael Kohrman

1. Qualifications

Dr. Michael H. Kohrman received a combined Bachelor of Science degree and Master of Science degree in chemistry from Stanford University in 1977. Ex. B (hereinafter "Kohrman CV" at 2). He graduated from Rush Medical College in 1981 with a degree in medicine. *Id.* From 1981 through 1983, Dr. Kohrman served as an intern, then a resident in pediatrics at the University of Chicago Hospitals and Clinics. *Id.* He also trained in a fellowship for pediatric neurology at the University of Chicago Hospitals and Clinic from 1983 through 1986. *Id.* Additionally, Dr. Kohrman trained in a fellowship for electroencephalography at the University of Illinois from 1986 to 1987. *Id.* He is board-certified in neurology, with a special competency in child neurology and sleep medicine and is also board-certified in pediatrics. *Id.* at 4. Currently, Dr. Kohrman serves as the Director of Child Neurology at Akron Children's Hospital and Professor of Pediatrics at Northeastern Ohio Medical University. Ex. A at 1. He previously directed the Epilepsy Program at Comer Children's Hospital at the University of Chicago and was Professor of Pediatric Neurology and Surgery. *Id*. He has been an attending physician providing care to children with epilepsy for over 30 years. *Id*. Dr. Kohrman has treated over 100 children with infantile spasms and thousands of children with epilepsy. *Id.* His current responsibilities are 80% clinical and 20% administrative. He attends on the Epilepsy service at Akron hospital 18 weeks per year and the focus of his practice is epilepsy (95%) and sleep medicine (5%). Dr. Kohrman has published more than 100 book chapters, professional abstracts, presentations, and papers. Kohrman CV at 2–17.

2. Expert Report

Dr. Kohrman submitted three expert reports in this case. Ex. A (hereinafter "First Kohrman Rep."), Ex. C (hereinafter "Second Kohrman Rep."), and Ex. D., (hereinafter "Third Kohrman Rep.").

a. First Kohrman Report

In his initial expert report, Dr. Kohrman observed that K.E.L.'s head circumference measurements decreased from the time of his birth to the date of his third DTaP vaccination. First Kohrman Rep. at 1-2. Specifically, Dr. Kohrman noted that K.E.L.'s head circumference was recorded at the 8th percentile on February 26, 2014, the date of his 3rd DTaP vaccine. *Id*. at 2.

Dr. Kohrman next provided a background summary on infantile spasms. First Kohrman Rep. at 5-6. He cited to an article written by Pavone, et al., that explains infantile spasms are an age-related disorder, and represent the most frequent type of epilepsy in the first year of life. *Id.* at 6. Pavone et al. described that the peak of infantile spasms occur between four and seven months, with 85% of the spasms ceasing before the age of five. *Id*. The clinical features of spasms include brief contractions, jerking, deviation of the eyes, and changes in respiratory patterns. *Id.* Developmental delay associated with infantile spasms is usually severe, although some patients have preserved cognitive profiles. *Id*. The etiology of infantile spasms remains elusive in some cases. Some noted causes of infantile spasms are hypoxic-ischemic encephalopathy (10%), chromosomal anomalies (8%), malformation (8%), perinatal stroke (8%), tuberous sclerosis complex (7%), and periventricular leukomalacia or hemorrhage (5%). *Id*. Dr. Kohrman noted that K.E.L. fits into a group with genotype unknown with progressive microcephaly noted early in life. *Id*.

In his assessment of K.E.L.'s case, Dr. Kohrman opined that K.E.L. had progressive microcephaly which predated all of his DTaP vaccinations, and thus, there is no evidence to suggest that his vaccinations changed the course of his disorder. First Kohrman Rep. at 8. He discussed Dr. Wilkerson's opinion that because no underlying cause was identified for K.E.L.'s infantile spasms, that vaccination must be the cause. Dr. Kohrman noted that in children with infantile spasms, only 64% had an identified underlying cause, meaning 36% of the children had no cause identified, like K.E.L. *Id*. at 9.

Dr. Kohrman also cited to the Institute of Medicine study that reviewed the question of a link between the DTaP vaccine and infantile spasms, noting that any association between the two was lacking. First Kohrman Rep. at 9. Dr. Kohrman concluded that based on the medical records, "there is no evidence that the DTaP [vaccine] caused [K.E.L.'s] microcephaly and seizure disorder and that the underlying progressive microcephaly predates vaccination as documented in the head circumference charts." *Id*.

b. Second Kohrman Report

In Dr. Kohrman's second report, responding to Dr. Wilkerson's supplemental report, he opined that K.E.L.'s head circumference measurements at birth and eight days later were essentially the same and would confirm the measurement as accurate. Second Kohrman Rep.at 2. He pointed out that the two-month head circumference measurement would require a very large measurement error, an entire two centimeters, to be at the 50% percentile, as the first two measurements were, thus inferring that the measurement was accurate and confirmed the onset of K.E.L.'s microcephaly prior to vaccination. *Id*.

Dr. Kohrman agreed with Dr. Wilkerson that skull growth is dependent on brain growth. Second Kohrman Rep. at 2. However, Dr. Kohrman stated that this fact supports the concept that K.E.L. had a preexisting brain disorder that caused his infantile spasms diagnosis. *Id*. Thus, K.E.L.'s progressive microcephaly confirms a process that was the cause of K.E.L.'s infantile spasms. *Id*.

Dr. Kohrman stated the medical literature demonstrates there is no specific correlation between the timing of the event that causes spasms, here microcephaly, and the actual onset of the spasms. Second Kohrman Rep. at 3. He pointed this out to refute Dr. Wilkerson's claim that a temporal association between K.E.L.'s third DTaP vaccine and the onset of his spasms established causation. *Id*. Citing to Guggenheim et al., Dr. Kohrman described a study where 19 published cases were identified to determine whether there was any such correlation. *Id*. at 3. The findings of the study refuted "claims that a close temporal association between an immunization and the onset of infantile spasms establishes causation." *Id*. at 4. Thus, Dr. Kohrman reiterated his conclusion that there is no evidence that the DTaP vaccine caused K.E.L.'s microcephaly and seizure disorder, and that the underlying progressive microcephaly predated K.E.L.'s third DTaP vaccination as documented in the head circumference charts. *Id*.

b. Third Kohrman Report

Dr. Kohrman filed a third expert report (Ex. D.) in response to questions I posed. My questions were as follows:

(1) Petitioners have alleged (among other injuries) that K.E.L. experienced an encephalopathy within 72 hours of the DTaP vaccine. Encephalopathy within 72 hours of vaccines containing DTaP is a Table injury. Dr. Wilkerson stated, "My conclusion is that the encephalopathy described in K.E.L. had onset at about six months." First Wilkerson Rep. at 7. He further opined that "the sum of evidence in this case is that, more likely than not, the insidious onset of his disorder, as best can be approximated, fell within a span of around three days, or seventy-two hours following the receipt of standard infantile immunization." *Id*. at 8. Please provide your opinion as to whether K.E.L. experienced an encephalopathy and if he did, when the encephalopathy began. Please also address whether that timing is or is not consistent with a vaccine reaction.

(2) Dr. Wilkerson discussed primitive reflexes that K.E.L. exhibited during an examination on June 14, 2014 (referencing Ex. 2 at 92). Dr. Ellsworth noted that K.E.L. exhibited "normal primitive reflexes." Dr. Wilkerson stated, "Primitive responses extinguish in developmentally normal infants at a point several months earlier than K.E.L. was at that point so that the presence of primitive responses at his then-current age was highly abnormal and indicative of an encephalopathy." First Wilkerson Rep. at 7. Do you agree with Dr. Wilkerson's position?

(3) Is there an association between microencephaly and infantile spasms?

With respect to the first question, whether K.E.L. experienced an encephalopathy within 72 hours of his third DTaP vaccine on February 26, 2014, Dr. Kohrman responded by summarizing

the well-child visits during this examination, as well as K.E.L.'s nine-month well-child visit. Third Kohrman Rep. at 1. At the six-month well-child visit, Dr. Kohrman observed that K.E.L.'s development was reported as normal – rolling, babbling, and sitting for a brief period. *Id*. At this time, K.E.L.'s head circumference had already dropped to the 8th percentile, although his weight was at the 40th percentile. *Id*. During the nine-month well child examination, K.E.L.'s development was likewise reported as normal – he was crawling, and saying "mama" and "dada", as well as standing with support transfers from hand to hand. *Id*. During the nine-month examination, K.E.L.'s head circumference measurement had further dropped to the third percentile, while his weight remained in the 40th percentile. *Id*. at 1-2. Dr. Kohrman opined as follows:

> His head circumference growth is the direct result of brain growth and this lack of head growth is consistent with abnormal brain development as the underlying cause of his Infantile spasms which began prior to vaccinations in question. K.E.L's developmental regression coincides with the onset of his infantile spasms. This is consistent with an epileptic encephalopathy caused by infantile spams which did not occur within 72 hrs of vaccination.

Id. at 3.

Dr. Kohrman stated that as defined by the vaccine injury table, "[a]n acute encephalopathy for acute encephalopathy for children less than 18 months of age who present without a seizure is indicated by a significantly decreased level of consciousness that lasts at least 24 hours. Following a seizure, an acute encephalopathy is demonstrated by a significantly decreased level of consciousness that lasts at least 24 hours and cannot be attributed to a postictal state—from a seizure or a medication." Third Kohrman Rep. at 2. Dr. Kohrman stated that the reports made by K.E.L.'s family – sleepiness, irritability (fussiness), high-pitched and unusual screaming, poor feeding, persistent inconsolable crying, etc., as well as seizures in and of themselves, are not sufficient to constitute a diagnosis of encephalopathy, either acute or chronic. *Id*. He opined that based on the medical records, "there is no evidence for an acute encephalopathy after vaccination on 2/26/2014 nor a chronic encephalopathy in the 3 months prior to onset of infantile spasms in June of 2014." *Id*.

Regarding Dr. Wilkerson's comments on primitive responses, he stated that Dr. Wilkerson misinterpreted the ER notation in the medical records. Third Kohrman Rep. at 2. The note from the ER visit indicated K.E.L. had "normal primitive reflexes for age". Dr. Kohrman opined that the more accurately worded notation would have been "no primitive reflexes" or "none." *Id*. Dr. Kohrman stated that this is the likely intention of the note as there were not primitive reflexes observed during K.E.L.'s six- and nine-month well-child visits. *Id*. In addition, there were no primitive reflexes noted by the neurologist who admitted K.E.L. for treatment of his infantile spasms. *Id*. Essentially, there is nothing in the record to support Dr. Wilkerson's interpretation of the note of "normal primitive reflexes for age." *Id*.

Dr. Kohrman did not answer my third question as to whether there is any association between microcephaly and infantile spasms. I note that in his initial report, Dr. Kohrman did state that K.E.L.'s "record demonstrates that he had progressive loss in head circumference

[microcephaly] from birth the etiology of which is unknown and is the etiology of his spasms." First Kohrman Rep. at 9.

V. Applicable Law

A. Petitioner's Burden in Vaccine Program Cases

Under the Vaccine Act, when a petitioner suffers an alleged injury that is not listed in the Vaccine Injury Table, a petitioner may demonstrate that he suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

In attempting to establish entitlement to a Vaccine Program award of compensation for an off-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner establish by preponderant evidence that the vaccination he received caused his injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278.

Under the first prong of *Althen*, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford v. Sec.'y of Health & Hum. Servs.*, 451 F.3d 1352,1355-56 (Fed. Cir. 2006) (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Proof that the proffered medical theory is reasonable, plausible, or possible does not satisfy a petitioner's burden. *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359-60 (Fed. Cir. Nov. 7, 2019).

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). However, special masters are "entitled to require some indicia of reliability to support the assertion of the expert witness." *Boatmon*, 941 F.3d at 1360, *quoting Moberly*, 592 F.3d at 1324. Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Hum. Servs.*, 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017); *see also Hock v. Sec'y of Health & Hum. Servs.*, No. 17-168V, 2020 U.S. Claims LEXIS 2202 at *52 (Fed. Cl. Spec. Mstr. Sept. 30, 2020).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion

testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause-and-effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"). As with expert testimony offered to establish a theory of causation, the opinions, or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

In determining whether a petitioner is entitled to compensation, a special master must consider the entire record and is not bound by any particular piece of evidence. § 13(b)(1) (stating that a special master is not bound by any "diagnosis, conclusion, judgment, test result, report, or summary" contained in the record). Furthermore, a petitioner is not required to present medical literature or epidemiological evidence to establish any *Althen* prong. The special master essentially must weigh and evaluate opposing evidence in deciding whether a petitioner has met their burden of proof. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1380 (Fed. Cir. 2009); *see also Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1149 (Fed. Cir. 1992).

B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's

report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are generally trustworthy because they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions," where "accuracy has an extra premium." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378 (Fed. Cir. 2021) citing *Cucuras*, 993 F.2d at 1528. This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825 at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) *mot. for rev. denied*, 142 Fed. Cl. 247, 251-52 (2019), *vacated on other grounds and remanded*, 809 Fed. Appx. 843 (Fed. Cir. Apr. 7, 2020).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475 at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475 at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825 at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*,

No. 90-2808V, 1998 WL 408611 at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires petitioners to present expert testimony in support of their claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (*citing Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted").

Respondent frequently offers one or more experts of his own in order to rebut petitioners' case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters

must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations").

D. Consideration of Medical Literature

Although this decision discusses some but not all of the medical literature in detail, I reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

V. Analysis

A. Dismissal for Failure to Prosecute and Failure to Follow Court Orders

Vaccine Rule 21(b)(1) provides that a "special master or the court may dismiss a petition or any claim therein for failure of the petitioner to prosecute or comply with these rules or any order of the special master or the court." Failure to follow court orders, as well as failure to file status reports or other required documents, can result in dismissal of petitioner's claim. *Tsekouras v. Sec'y of Health & Hum. Servs.,* 26 Cl. Ct. 439 (1992), *aff'd per curiam*, 991 F.2d 810 (Fed. Cir. 1993); *Sapharas v. Sec'y of Health & Hum. Servs.*, 35 Fed. Cl. 503 (1996); Vaccine Rule 21(b).

Petitioners have not communicated with my chambers since January 31, 2022, despite numerous orders to do so and a show cause order, notifying them that their case would be dismissed if they did not respond. While I could dismiss their case on this basis alone, I have conducted a substantive analysis, detailed below.

B. Resolution of Case Without a Hearing

Because Petitioners stopped communicating with my chambers, I have opted to determine entitlement in this case based on evidentiary filings, including the medical records, the affidavits, and the expert reports and medical literature filed by each side. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on papers rather than via evidentiary hearing, when they conclude that the former means of adjudication will properly and fairly resolve the case. § 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See Hooker v. Sec'y of Health & Hum. Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of a hearing). A hearing is not required in every matter, regardless of the parties' preferences. *See Hovey v. Sec'y of Health & Hum. Servs.*, 38 Fed. Cl. 397, 400-01 (1997) (determining that the special master acted within his discretion in denying evidentiary hearing), *appeal dismissed*, 135 F.3d 773 (Fed. Cir. 1997); *Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993); *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL

71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991), *mot. for rev. denied*, 23 Cl. Ct. 726 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992).

A hearing provides a petitioner with the opportunity to present live testimony, which aids the special master most in cases where witness credibility is at issue, or where there is a need to pose questions to a witness in order to obtain information not contained in, or not self-evident from, the existing filings. *See, e.g.*, *Hooker*, 2016 WL 3456435, at *21 (discussing the factors that weigh against holding a hearing); *Murphy*, 1991 WL 71500, at *2 (finding no justification for a hearing where "the claim is fully developed in the written record and the special master sees no need to observe the fact witnesses personally for the purpose of assessing credibility). Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to afford each party "a full and fair opportunity to present its case." *Hovey*, 38 Fed. Cl. at 401. But that rule also includes the obligation to create a record "sufficient to allow review of the special master's decision." *Id.* Thus, the fact that a claim is legitimately disputed, such that the special master must exercise her intellectual faculties in order to decide a matter, is not itself grounds for a trial. Special masters are expressly empowered to resolve fact disputes without a hearing, and they may do so if the record at issue has been sufficiently developed to determine that each side's "full and fair" opportunity has not been abridged.

In this case, live witness testimony was not required in order for me to reach a reasoned decision on entitlement. The record itself contained sufficient evidence upon which to base this decision. The flaws in Petitioners' theory and factual arguments were self-evident from review of the medical records and the expert reports submitted, which relied heavily on speculative assertions and statements unsupported by the contemporaneous medical record or by reliable scientific evidence. I simply do not require additional oral testimony to decide the case. Ultimately, the most significant issue in deciding whether to hold a hearing is whether the refusal to do so will deprive the claimants of the fair opportunity to prosecute their case. Petitioners have received such an opportunity here. Therefore, these circumstances counsel in favor of resolving the matter on the papers.

C. Table Claim

In a Table encephalopathy claim, Petitioners must first demonstrate that K.E.L. received a covered vaccine. Next, Petitioners must demonstrate that K.E.L. suffered an injury corresponding to the covered vaccine within the specified time period. Here, the Table lists an encephalopathy as an injury arising from the DTaP vaccine if the injury occurs within three days of the vaccination. *See* 42 C.F.R. § 100.3(a). The definition of encephalopathy under the Vaccine Table is a narrower interpretation than what is commonly accepted in the medical community. Under the Qualifications and Aids to Interpretation ("QAI") of the Vaccine Table, a Table encephalopathy occurs where the vaccinee suffers an acute encephalopathy, followed by a chronic encephalopathy for more than six months, or death. 42 C.F.R. § 100.3(a)-(b)(2).

Petitioners allege that K.E.L. suffered from the Table injury, encephalopathy within 24 hours of receiving his third DTaP vaccine. The QAI defines "acute encephalopathy" as "one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred.) 42

C.F.R. § 100.3(b)(2)(i). For children who are less than 18 months of age, which includes K.E.L., "an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours." 42 C.F.R. § 100.3(b)(2)(i)(A). The definition of the phrase "significantly decreased level of consciousness" is found in paragraph D, which states:

> A "significantly decreased level of consciousness" is indicated by at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (2)(i)(A) and (2)(i)(B) of this section for applicable time frames.
>
> (1) Decreased or absent response to environment (response, if at all, only to loud voice or painful stimuli);
>
> (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
>
> (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things.)

42 C.F.R. § 100.3(b)(2)(i)(D); *see also Waddell*, 2012 WL 4829291, at 7 (holding that the QAI definition of "significantly decreased level of consciousness" implies "a state of diminished alertness that is much more than mere sleepiness or inattentiveness...[It] requires markedly impaired – or strikingly absent – responsiveness to environmental or external stimuli for a sustained period of at least twenty-four hours.")

> The following have been excluded as features that demonstrate an encephalopathy.
>
> The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

42 C.F.R. § 100.3(b)(2)(i)(E), *see also Watt v. Sec'y. of Health & Hum. Servs.* No. 99–25V, 2001 WL 166636, at 8 (Fed. Cl. Spec. Mstr. Jan. 26, 2001) (explaining that a Table encephalopathy "cannot merely be crying" and "it cannot merely be crankiness").

I note again that the QAI specifically exclude the presence of seizures as evidence of an acute encephalopathy: "Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy and in the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of an acute encephalopathy." 42 C.F.R. § 100.3(b)(2)(i)(D).

Petitioners allege that K.E.L.'s claim should be considered a Table injury, arguing that the third DTaP vaccine administered to K.E.L. on February 26, 2014, caused encephalopathy. Petitioners appear to allege that K.E.L.'s presentation of "uncontrollable" crying, jerking spells, startling, and painful responses that occurred "in the last few days of February" are manifestations of the onset of his Table encephalopathy. Petition at 2; Ex. 4 at 2 (Lisa Lindholm affidavit); Ex. 5 at 1-2 (Erik Lindholm affidavit). In the post 72-hour period, approximately March 4, 2014, Petitioners allege that K.E.L. acted lethargically, absent-mindedly, and seemed not to notice or recognize his parents or siblings. Petition at 2, ¶ 4; Ex. 4 at ; Ex. 28 at 1 (Lisa Lindholm Supp. Aff.).

Unfortunately, Petitioners' expert, Dr. Wilkerson, did little to clarify which behaviors K.E.L. exhibited in the 72 hours after vaccination that constitute the onset of an acute encephalopathy. Rather, Dr. Wilkerson acknowledged that the behaviors constituting the onset of encephalopathy are "too vague and subtle to be initially perceived as abnormal by parents." First Wilkerson Rep. at 6. Dr. Wilkerson simply posited that "an approximation of onset of K.E.L.'s spasms and behavior changes within the week or so after the time of immunization, as described in the petitioner's affidavit, is as close a fit with the NVICP criteria as can be reasonably expected …" *Id*.

Respondent's expert, Dr. Kohrman, stated that "the symptoms of K.E.L.'s epileptic encephalopathy are noted in the medical record to begin in May to June of 2014, two months after his third DTaP vaccination." First Kohrman Rep. at 8. An epileptic encephalopathy is not an acute encephalopathy as defined by the Table. Even if it were, Dr. Kohrman opined that the onset of the disorder began in May or June 2014, approximately two months after vaccination. *Id*.

Ultimately, the evidence does not demonstrate that K.E.L. suffered a Table encephalopathy. As former Chief Special Master Campbell-Smith noted in *Waddell v. Sec'y of Health & Hum. Servs.*, the symptoms of a Table encephalopathy are "neither subtle nor insidious." No. 10-316V, 2012 WL 4829291, at *6 (Fed. Cl. Spec. Mstr. Sept. 19, 2012). In reviewing and evaluating all of the behaviors and symptoms that K.E.L. exhibited in the 72 hours post vaccination, including all information reported in the medical records, the witness affidavits, and the information contained in the parties' respective expert reports, it is apparent that none of these behaviors constitute an acute encephalopathy as defined by the Vaccine Table. In fact, the particular behaviors K.E.L. did exhibit as testified to by his parents, such as inconsolable crying, jerking spells, and/or manifestation of any type of seizure activity, are specifically excluded as behaviors constituting the onset of an acute encephalopathy as described in the QAI.

Moreover, while Petitioners allege that K.E.L. exhibited unusual behaviors such as "uncontrollable" crying, jerking spells, startling, and painful responses that occurred "in the last few days of February", there are no medical records that support their claim. After being vaccinated on February 26, 2014, K.E.L. was not seen for more than one month, 35 days later, when he was brought to his pediatrician, Dr. Eischens, for complaints of decreased appetite, coughing, "not acting himself" which, as Petitioners reported, started four days prior. Ex. 27 at 5. There is no mention at this visit of any unusual behaviors in the few days or even first few weeks after vaccination.

At K.E.L.'s nine-month well child visit, he was noted to be a "happy, healthy baby" with "good bonding with mom." Ex. 27 at 9. He was meeting developmental milestones and was not scheduled for another visit until his one-year visit several months later. *Id*. at 12. These records are in direct contradiction with Petitioners and the witness affidavits presented. Although Ms. Lindholm stated that she called Dr. Eischens's office more than once to inquire about "abnormal jerking spells", Ms. Lindholm admits that she has no telephone records to support these statements and Dr. Eischens's notes and records make no mention of these reports. Ex. 28 at 1.

I am bound by the evidence before me and unfortunately, there is not a preponderance of evidence to support Petitioners' claim that K.E.L. suffered an encephalopathy within 72 hours of his third DTaP vaccination on February 26, 2014. Thus, Petitioners' Table claim must fail.

D. Causation in Fact

Because Petitioners have not proven that K.E.L. suffered a Table injury, they must show that he sustained an injury that was actually caused by the vaccine he received. To do so, they must establish, by preponderant evidence: (1) a medical theory causally connecting the DTaP vaccine to K.E.L.'s injury ("*Althen* Prong One"); (2) a logical sequence of cause and effect showing that the DTaP vaccine was the reason for his injury ("*Althen* Prong Two"); and (3) a proximate temporal relationship between the DTaP vaccine and his injury ("*Althen* Prong Three"). *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Petitioners must prove all three prongs by a preponderance of the evidence. For the reasons set forth below, I find that Petitioners have failed to satisfy the *Althen* test and are therefore not entitled to compensation.

1. *Althen* Prong One: Petitioners have not Provided a Reliable and Reputable Theory Concerning Whether the Vaccine K.E.L. Received Can Cause Encephalopathy and Infantile Spasms

Under *Althen* prong one, Petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Proof that the proffered medical theory is plausible or possible does not satisfy a petitioner's burden. *Boatmon v. Sec'y of Health & Hum. Servs*., 941 F.3d 1351, 1359-60 (Fed. Cir. Nov. 7, 2019).

Petitioners may satisfy this prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). However, special masters are "entitled to require some indicia of reliability to support the assertion of the expert witness." *Boatmon*, 941 F.3d at 1360, *quoting Moberly*, 592 F.3d at 1324. Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from

the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Hum. Servs.*, 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017); *see also Hock v. Sec'y of Health & Hum. Servs.*, No. 17-168V, 2020 U.S. Claims LEXIS 2202 at *52 (Fed. Cl. Spec. Mstr. Sept. 30, 2020).

In evaluating the totality of the evidence in this case, I conclude that Petitioners have failed to provide preponderant evidence of a medical theory that satisfies *Althen* prong one.

Dr. Wilkerson opined that vaccines can trigger an "unspecified immune mechanism" in the individual, although "the exact immune mechanism remains elusive...." First Wilkerson Rep. at 3. Instead of describing a theory as to how the DTaP vaccine can cause a condition like the one that K.E.L. experienced, Dr. Wilkerson merely concluded that it was so. His report offers textbook examples of conclusory opinions. In his first report, for instance, he made the following assertion:

> while lacking absolute scientific proof that vaccine causes brain injury in any case, nevertheless, the preponderance of evidence in this case, at the current level of scientific understanding about likely mechanisms by which vaccine content may cause brain injury, supports the medical conclusion that, more likely than not, there is a significant causal contribution to the encephalopathy present in K.E.L. which is attributable to the immediate proximate vaccine administered to him in late February 2014. Stated differently, more likely than not, but for the vaccine administration of February 2014, K.E.L. otherwise would not have developed infantile spasms or the related encephalopathy.

Id. at 9.

Dr. Wilkerson did not explain how the DTaP vaccine can cause infantile spasms, encephalopathy, or any kind of brain injury. Similarly, in his second expert report, Dr. Wilkerson offered a two-sentence conclusion as a theory:

> I retain the opinions expressed in my initial report that K.E.L. has a severe encephalopathic process with onset at point proximate to his age of 6 months and the administration of his third vaccine dose of the DTaP. More specifically, my conclusion is that the available evidence submitted by the Petitioner does fulfill the specific medical criteria for compensation under the NVIC.

Second Wilkerson Rep. at 4. Again, Dr. Wilkerson failed to explain how the DTaP vaccine can cause an immune-mediated injury such as infantile spasms and encephalopathy.

When evaluating whether Petitioners have carried their burden of proof, special masters consistently reject "conclusory expert statements that are not themselves backed up with reliable scientific support." *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, No. 08-209V, 2018 WL 3679843, at *32 n.44 (Fed. Cl. Spec. Mstr. June 22, 2018). Special masters cannot rely on "opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Moberly v. Sec'y*

of Health & Hum. Servs., 85 Fed. Cl. 571, 596 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997)), *aff'd*, 592 F.3d 1315 (Fed. Cir. 2010). Instead, special masters are expected to carefully scrutinize the reliability of each expert report submitted. *See id.*

I am cognizant that Petitioners do not have to provide a specific mechanism of injury, however their theory must be detailed enough to apply to the specific vaccine and injury in this case. Otherwise, any vaccine, by virtue of the fact that it elicits an immune response, could be asserted as the cause of any autoimmune disease. *See W.C. v. Sec'y of Health & Hum. Servs.,* 704 F.3d 1352, 1360 (2013) (finding that a petitioner cannot prevail by simply invoking a biological term, or by showing that the mechanism is a valid theory to explain how *other* triggers may have induced *other* diseases and determining that a petitioner must produce additional evidence that the mechanism can cause that vaccine to cause a specific disease); *Caves v. Sec'y of Health & Hum. Servs.,* 100 Fed. Cl. 119, 135 (2011), *aff'd*, 463 F. App'x. 932 (2012); *McKown v. Sec'y of Health & Hum. Servs.,* No. 15-1451, 2019 WL 4072113, *50 (Fed. Cl. Spec. Mstr. July 15, 2019).

Dr. Wilkerson's statement that vaccines can trigger an "unspecified immune mechanism" is not a cognizable theory. Petitioners have not provided a sound and reliable medical theory explaining how the DTaP vaccine can cause infantile spasms or encephalopathy. His reports amount to no more than *ipse dixit*, and as such are insufficient for Petitioners to meet their burden under *Althen* prong one.

2. *Althen* Prong Two

Althen prong two requires the Petitioners to establish a logical sequence of cause and effect demonstrating that the vaccination did cause K.E.L's condition. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause-and-effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

The evidence in this case suggests that K.E.L.'s infantile spasms, seizure disorder, and resultant developmental delays were likely caused by abnormal brain development and progressive microcephaly, which the evidence suggests existed prior to K.E.L.'s third DTaP vaccination on February 26, 2014. The existence of this prior condition reduces the persuasiveness of Petitioners' showing that the vaccine "did cause" K.E.L.'s condition. *See K.L. v. Sec'y of Health & Hum. Servs.,* 134 Fed. Cl. 579, 598 (Fed. Cl. 2017) ("regardless of whether the burden of proof ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a *prima facie* case") (internal citations omitted).

For the reasons discussed below, the evidence likewise demonstrates that the DTaP vaccine did not cause K.E.L.'s microcephaly, infantile spasms, and developmental delay.

Petitioners contend that the second *Althen* prong has been satisfied because no other cause for K.E.L.'s condition was identified. Dr. Wilkerson's report presupposes that because most other possible causes had been ruled out, the vaccine must have been the cause of K.E.L.'s infantile spasms and corresponding brain and developmental abnormalities. Specifically, Dr. Wilkerson opined as follows:

> the medical record, specifically the record of the Mayo Clinic evaluation, clearly satisfies the elimination of all known and identifiable causes of the encephalopathy in K.E.L. to the level of current medical scientific ability … Since the findings of that evaluation eliminate all currently known alternative causes other than that of vaccine injury as the basis of the encephalopathy manifest in K.E.L., the results of that evaluation are consistent with the hypothesis of vaccine-related brain injury as its cause but, absent a consensus accepted biologic marker of vaccine-related brain injury, the hypothesis of vaccine-related brain injury was not scientifically proven.

Id. at 3. This process of elimination of other potential causes, or a diagnosis of exclusion, does not satisfy *Althen* prong two. The Federal Circuit has explained that "[a]lthough probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." *Althen*, 418 F.3d at 1278 (citing *Grant*, 956 F.2d at 1149).

i. K.E.L. Experienced Evidence of Microcephaly Beginning at Approximately Two Months of Age

Microcephaly is defined as "abnormal smallness of the head, usually associated with intellectual disability." Dorland. (2011). *Dorland's Illustrated Medical Dictionary E-Book. London*: Saunders. The medical records show that at birth, August 19, 2013, K.E.L.'s head circumference was 34.29 centimeters (over the 50th percentile). Ex. 2 at 14, 16. Nine days later, K.E.L.'s head circumference was nearly the same, measured at 34.30 centimeters. Ex. 6 at 1-2. By two months of age, K.E.L.'s head circumference had dropped to the 10th percentile, measuring at 38.10 centimeters. Ex. 6 at 1-2.

At the time of K.E.L.'s third DTaP vaccination on February 26, 2014, K.E.L.'s head circumference had dropped to the 8th percentile, measuring at 41.90 centimeters. Ex. 6 at 1-2. His overall development was otherwise described as normal. Ex. 27 at 2.

As Dr. Kohrman noted in his first report, K.E.L. had evidence of progressive microcephaly documented in his medical records starting at age two months, which pre-dates the administration of the third DTaP vaccine on February 26, 2014. First Kohrman Rep. at 8. Dr. Kohrman observed that K.E.L.'s head circumference decreased from above the 50th percentile at birth to the 10th percentile on October 28, 2013, the date of his very first DTaP vaccine. *Id*.

Although Dr. Wilkerson disputed Dr. Kohrman's claim that K.E.L.'s microcephaly was evident at two months of age, his reasoning, which presumes the mismeasurement of head circumference by K.E.L.'s doctors, is not persuasive. Dr. Wilkerson suggested that the likelihood of mismeasurement of head circumference in K.E.L.'s circumstances was high, although there is

no evidence to suggest this occurred. To the contrary, the head circumference measurements from birth to eight days of age are nearly identical, indicating that the head circumference measurements were accurate. Dr. Wilkerson also suggested that K.E.L.'s head circumference measurements may have been entirely normal, as large and small head measurements alike are sometimes seen in completely normal patients. While this observation is no doubt true, there is no dispute that K.E.L. eventually developed microcephaly, and thus, the likelihood that his small head circumference at two months of age was a simple anomaly is not persuasive.

Dr. Kohrman also stated that K.E.L.'s symptoms of epileptic encephalopathy were noted in the medical records to begin in May and June of 2014, approximately two months after receipt of his third DTaP vaccine. First Kohrman Rep. at 8. Dr. Kohrman opined that developmental delay and regression may precede, follow, or begin at the time spasms begin as is noted in the medical literature. *Id*. There is no known temporal association between a brain injury and the onset of infantile spasms, which will be discussed more fully in *Althen* prong three.

ii. K.E.L.'s Abnormal Brain Development is the Most Likely Cause of his Infantile Spasms

Dr. Kohrman stated that K.E.L.'s clinical course was "quite typical of cryptogenic infantile spasms…" First Kohrman Rep. at 9. He persuasively opined that K.E.L.'s medical records demonstrate he had progressive loss in head circumference from birth, the etiology of which is unknown as is the etiology of his spasms. *Id*. With infantile spasms, Dr. Kohrman noted that "overall 80% of infants with spasms have persistent development delays even with ideal treatment. Lennox-Gastaut syndrome occurs in approximately half of infants diagnosed with spasm and over 90% have continued seizures after the age of 10 years." Second Kohrman Rep. at 2. Dr. Kohrman also confirmed that K.E.L.'s

> head circumference growth is the direct result of brain growth and this lack of head growth is consistent with abnormal brain development as the underlying cause of his infantile spasms which began prior to vaccinations in question. This is consistent with an epileptic encephalopathy caused by infantile spasms which did not occur within 72 hours of vaccination.

Third Kohrman Rep. at 3. I find this opinion to be persuasive.

Ultimately, preponderant evidence supports the fact that K.E.L.'s microcephaly began before receipt of his third DTaP vaccine on February 26, 2014. Further, a preponderance of the evidence demonstrates that K.E.L.'s microcephaly is evidence of abnormal brain development that existed prior to vaccination, and which, more likely than not, resulted in the development of infantile spasms and resultant developmental delay.

For the reasons discussed in this decision, I find that Petitioners have failed to establish the second *Althen* prong.

3. *Althen* Prong Three

Althen prong three requires Petitioners to establish a "proximate temporal relationship" between K.E.L.'s condition and the vaccine he received. *Althen*, 418 F.3d at 1281. Petitioners must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.,* 539 F.3d 1347, 1352 (Fed. Cir. 2008).

The timing prong contains two parts. First, Petitioners must establish the "timeframe for which it is medically acceptable to infer causation" and second, they must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec'y of Health & Hum. Servs.,* 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013).

i. The Onset of K.E.L.'s Condition

Dr. Wilkerson explained in detail in his first expert report that identifying the precise timing of the onset of infantile spasms is "exceedingly difficult". First Wilkerson Rep. at 4. Dr. Wilkerson discussed, for nearly half of his report, the subtleties of recognizing signs of the onset of the disorder, which "for numerous reasons invariably are unrecognized for quite some time." *Id*. at 5. He explained that the initial spasms are "fleeting in duration" and sometimes only produce "a nod of the head or a barely perceptible jerk or movement of the shoulders, trunk or hips." *Id*. He also explained that a typical infant already demonstrates normal jerky movements at various stages of infancy and thus, seizures may go undetected. *Id*. Despite Dr. Wilkerson's extensive discussion about the difficulty of identifying the precise onset of infantile spasms, he initially stated the following with respect to the onset of K.E.L.'s condition:

> Thus, an approximation of onset of K.E.L.'s spasms and behavioral changes within the week or so after the time of immunization, as described in the petitioner's affidavit, is as close a fit with the NVICP criteria as can be reasonably expected given the above discussed peculiarities of infantile spasms and the diagnostic constraints of bystander recognition.

First Wilkerson Rep. at 6. Two pages later, Dr. Wilkerson shortened this onset window to conform with the Vaccine Injury Table. He opined that K.E.L.'s infantile spasms "more likely than not … as best can be approximated, fell within a span of around three days, or seventy-two hours following the receipt of standard infantile immunization." *Id*. at 8. Dr. Wilkerson did not explain his shift from "within the week or so after the time of immunization" to "within a span of around three days" following vaccination.

More importantly, Dr. Wilkerson failed to explain how he arrived at either conclusion. He provided no citations in the medical records to support his opinion that onset occurred either within one week or three days post-vaccination. In fact, Dr. Wilkerson stated that the first note of a neurodevelopmental abnormality in K.E.L. was documented in the medical records when K.E.L. was eight or nine months of age ("[t]he first medically recorded note of neurodevelopmental abnormality was the report of persisting neonatal responses described when K.E.L. was around eight- or nine-months age"). Second Wilkerson Rep. at 2. The only information that Dr. Wilkerson could have relied upon for a three day/72-hour onset of K.E.L.'s infantile spasms is Petitioners'

own statements reporting K.E.L.'s unusual behavior occurring during the several days and weeks following vaccination; reporting which is directly contradicted by the contemporaneous medical records, which establish onset of K.E.L.'s condition about one month before his mid-June 2014 medical appointment ((*e.g.*, Ex. 2 at 92 – On June 14, 2016, Ms. Lindholm reported that for the last month [approximately May 15, 2016], K.E.L. had been "pretty lazy and laying around a lot."; Ex. 25 at 40 – On June 19, 2016, the medical record states "[t]his is a previously healthy 10-month-old who had been well in his normal state of health up until a month back [approximately May 19, 2016] when the mother noticed that he was not acting himself anymore."; Ex. 25 at 50 - A progress note dated June 20, 2014, stated that "[t]his is a 10-month-old male who was in a normal state of health until a month prior [approximately May 20, 2016] when he began having increased lethargy, increased abnormal movement episodes which appear in clusters at times."; Ex. 8 at 109 – The earliest reported onset by the Petitioners was during the intake process at the Mayo clinic evaluation in April 2015, nearly a year later, when K.E.L.'s mother reported that K.E.L. started to have epileptic spasms in March 2015).

In order to overcome the presumption that contemporaneous written medical records are accurate, testimony must be "consistent, clear, cogent, and compelling." *Blutstein*, 1998 WL 408611, at *5. Because of this presumption, "special masters in this Program have traditionally declined to credit later testimony over contemporaneous records." *Sturdivant v. Sec'y of Health & Hum. Servs.,* No. 07-788V, 2016 WL 552529, at *15 (Fed. Cl. Spec. Mstr. Jan. 21, 2016). *See, e.g., Stevens v. Sec'y of Health & Hum. Servs*., No. 90–221V, 1990 WL 608693, at *3 (Fed. Cl. Spec. Mstr. Dec. 21, 1990); *see also Vergara v. Sec'y of Health & Hum. Servs*., No. 08–882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. Jul. 17, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony."); *See also, Cucuras*, 993 F.2d at 1528 (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight").

Importantly, this is not a case where the Petitioners failed to report K.E.L.'s condition to a physician. They presented K.E.L. for treatment and consistently told each treating physician that K.E.L. began to experience symptoms about one month prior. These affirmative statements regarding onset are significant: "it must be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." *Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (Fed. Cl. 1991)(*aff'd* 968 F.2d 1226 (Fed. Cir. 1992)). I find these repeated statements to medical providers to be more persuasive than Petitioners' affidavits prepared in anticipation of litigation.

Dr. Wilkerson's conclusion that the onset of K.E.L.'s infantile spasms began either 72 hours or within one week post vaccination is not persuasive. Ultimately, the preponderance of the evidence in this case demonstrates that K.E.L. began experiencing infantile spasms in mid-May of 2014.

ii. The Timeframe for which it is Medically Acceptable to Infer Causation

As discussed earlier in this decision, there is a notable absence of a medical causation presented by the Petitioners. Just as Dr. Wilkerson did not articulate a theory as to how the DTaP

vaccine can cause infantile spasms, he also did not provide any meaningful explanation of a medically appropriate temporal interval.

Petitioners have not established either the timeframe for which it is medically acceptable to infer causation or that the onset of K.E.L.'s condition occurred during this period. Accordingly, Petitioners have not presented preponderant evidence in support of the third *Althen* prong.

VI. CONCLUSION

Petitioners have experienced great suffering as a result of K.E.L.'s condition. However, in order to find they are entitled to compensation they must preponderantly demonstrate that the vaccines caused K.E.L.'s condition. Based on the evidence presented in this case, I conclude that Petitioners have not made such a showing. **Their petition is therefore DISMISSED. The clerk shall enter judgment accordingly.** [10]

A copy of this Decision shall be sent to Petitioners via U.S. Mail. to the following address:

Erik and Lisa Lindholm
22920 462nd Avenue
Wentworth, SD 57075

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master

[10] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of a notice renouncing the right to seek review.